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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,170	12/22/2003	Anke Esperester	1/1445US	7746

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,170	ESPERESTER ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-30* is/are pending in the application.

4a) Of the above claim(s) *17-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-16 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/3/07 has been entered.

Claims 1 and 4-31 are pending in the application, claim 31 being newly added in the amendment filed with the RCE of 5/3/07.

Claims 17-28 remain withdrawn from examination on the merits, having been elected without traverse on 9/25/05.

New claim 31 is properly placed in Group I invention, with claims 1, 4-16 and 29-30.

Claims 1, 4-16 and 29-31 were examined on their merits.

Previous rejections not repeated below were removed based upon Applicant's persuasive arguments. It is conceded that Ables did not teach an extract 'consisting essentially of ingredients of an aqueous extract of red vine leaves'.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-16 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilgrami et al. (1993) in view of Struengmann (US 6,284,269).

Bilgrami et al. (1993) studied the preventative effects of aqueous *Vitis vinefera* L. leaf. (red vine leaf) on nephrotoxicosis due to ingestion of the micotoxin citrinin. Bilgrami et al. discovered that *V. vinefera* L. leaf water extract administered by intubation to albino Swiss mice challenged with citrinin possessed greater toxicity prevention than cortisone (see entire reference, especially Table 1 and p. 482, col. 2).

Bilgrami et al. did not specifically teach wherein the red vine leaf water extract was contained in a tablet with a disintegrant such as colloidal, anhydrous silica, a binder such as microcrystalline cellulose, a filler such as hydrogen phosphate or magnesium stearate, a plasticizer, a colorant or the particular amounts of each constituent in the tablet.

Struengmann (US 6,284,269) disclosed conventional tablet additives such as hydrogen phosphate, colloidal anhydrous silica, sodium starch, magnesium stearate, microcrystalline cellulose (see example V/7, col's 10-11) as well as plasticizers such as polyethylene glycol (see claim 10). Thus, it was known that all of the tablet ingredients as Instantly claimed were conventional tablet ingredients, known at the time the invention was made.

Mathowitz, E. (1999) disclosed the conventional practice of addition of controlled-release coatings (films) in tablet manufacture (see pages 302 and 306-309).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal concentrations of components because concentration of aqueous red vine leaf extract is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. Although the prior art do not teach the particular combination of carriers which are added to the red vine extract or all the various permutations of concentration ranges as claimed, it would be conventional and within

the skill of the art to identify the optional concentrations of a given excipient because (1) the selection of appropriate concentration of excipients to stabilize red vine extract for the intended purpose of preventing its denaturation and decomposition during storage are conventional and within the skill in the art, and (2) hydrogen phosphate, colloidal anhydrous silica, sodium starch, magnesium stearate, microcrystalline cellulose and polyethylene glycol are well known in the art as excipients to used for tableting active ingredients. The incorporation of known active ingredients into tablets with conventional carriers was well within the purview of the ordinary artisan at the time the invention was made, and is hence considered *prima facie* obvious.

It would have further been obvious to create a tablet comprising aqueous red vine leaf extract with an enteric coating in order to shield the active ingredients of the extract from the acidic environment of the stomach in order to allow the active ingredients to pass undestructed into the small intestine for absorption into the bloodstream. It is clear from the teachings of Bilgrami et al. that the active ingredients enter into the bloodstream. Therefore, one of ordinary skill in the art would have easily recognized that protection of the extract would have been advantageous in order to prevent the degradation of the active components in order to optimize the effectiveness of the medicinal extract.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

June 3, 2007